		Case 1:14-cv-00124-JFM Document	1 Filed 04/11/13 Page 1 of 32		
	1 2 3 4 5 6 7 8 9	BLOOD HURST & O'REARDON, LITIMOTHY G. BLOOD (149343) THOMAS J. O'REARDON II (247952701 B Street, Suite 1700 San Diego, CA 92101 Telephone: 619/338-1100 619/338-1101 (fax) tblood@bholaw.com CARPENTER LAW GROUP TODD D. CARPENTER (234464) 402 West Broadway, 29th Floor San Diego, California 92101 Telephone: 619/347-3517 619/756-6991 (fax) todd@carpenterlawyers.com Attornevs for Plaintiff and the Class	G		
LLP	11	UNITED STATES DISTRICT COURT			
DON,	12	SOUTHERN DISTR	RICT OF CALIFORNIA		
REAR	13	ROBERT DORFMAN, On Behalf of	Case No.: '13CV0873 WQHRBB		
BLOOD HURST & O'REARDON, LLP	14	ROBERT DORFMAN, On Behalf of Himself and All Others Similarly Situated,			
JRST (15	Plaintiff,	<u>CLASS ACTION</u>		
D Ht	16	v.	CLASS ACTION COMPLAINT FOR: 1. VIOLATION OF CONSUMERS		
BLOC	17	NUTRAMAX LABORATORIES,	LEGAL REMEDIES ACT, CIVIL		
щ	18	INC. WAL-MART STORES, INC., and RITE-AID CORPORATION,	CODE §1750 et seq.; 2. VIOLATION OF THE UNFAIR		
	19	Defendants.	COMPETITION LAW, BUSINESS AND PROFESSIONS		
	20		CODE §17200 et seq.; and		
	21		3. BREACH OF EXPRESS WARRANTY.		
	22		DEMAND FOR JURY TRIAL		
	23 24		DEMAND FOR JUNE TRIAL		
	25				
	26				
	27				
	28				
0007017			Case No.		
00058494		CLASS ACTIO	ON COMPLAINT		

Plaintiff Robert Dorfman brings this action on behalf of himself and all others similarly situated against Defendant Nutramax Laboratories, Inc. ("Nutramax"), Wal-Mart Stores, Inc., and Rite-Aid Corporation (collectively "Defendants") and states:

NATURE OF ACTION

- 1. Defendants distribute, market and sell Nutramax's "Cosamin" line of glucosamine-based products marketed as "Joint Health Supplements." Defendants claim Cosamin provides a variety of significant health benefits for the cartilage and joints of all consumers who ingest Cosamin. These claimed health benefits are the only reason a consumer would purchase Cosamin. Defendants' advertising claims, however, are false, misleading, and reasonably likely to deceive the public.
- 2. Defendants represent that the primary active ingredients in its Cosamin products are "glucosamine," and "chondroitin sulfate." Through an extensive and uniform nationwide advertising campaign, Defendants represent that Cosamin "is the only brand proven effective in controlled, published U.S. studies to reduce joint pain," and that it has been "[s]hown in laboratory tests to protect cartilage cells from breakdown." *See* Product Label, Cosamin DS attached hereto as Exhibit "A". Defendants further warrant that the product "works better" and "lasts longer" purportedly than other similar competitor products.
- 3. All available scientific evidence demonstrates that the Cosamin products have no efficacy at all, are ineffective in the improvement of joint health, and provide no benefits related to the reduction of pain in human joints or protecting cartilage from breakdown. In fact, Defendants do not have any competent, reliable scientific evidence that substantiates their representations about the health benefits of consuming Cosamin. Numerous scientifically valid studies have been conducted on the ingredients, including the core or primary

ingredient in Cosamin, glucosamine hydrochloride, and they have universally demonstrated that glucosamine and glucosamine in combination with other ingredients such as chondroitin and chondroitin sulfate have absolutely no scientific value in the treatment of joint pain or discomfort.

- 4. Defendants represent that the active ingredients in Cosamin products provide relief for joint pain and osteoarthritis. The product labeling states, that it will "protect your cartilage" and "reduce joint pain". *See* product label, attached as Exhibit "A". These bold claims are in addition to other misrepresentations claiming that it is the only brand "proven effective in controlled, published U.S. studies to reduce joint pain." Defendants also represent throughout the Cosamin advertising that Cosamin is the "#1 brand recommended by Orthopedic Specialists," implying that there is legitimate science substantiating the joint health and cartilage marketing claims.
- 5. Defendants convey their uniform, deceptive message to consumers through a variety of media including their websites and online promotional materials, and, most important, at the point of purchase, on the front of the Products' packaging/labeling where it cannot be missed by consumers. The front of the Cosamin product label states in bold print, "Protect your cartilage with the only brand proven to reduce joint pain." The only reason a consumer would purchase Cosamin is to obtain the advertised joint-health benefits, which the Cosamin products do not provide.
- 6. As a result of Defendants' deceptive advertising and false claims regarding the efficacy of the Cosamin product, Plaintiff and the proposed class have purchased a product which does not perform as represented and they have been harmed in the amount they paid for the product, which, in the case of Plaintiff Dorman is approximately thirty five dollars.
- 7. Plaintiff brings this action on behalf of himself and other similarly situated consumers who have purchased the Cosamin products to halt the

dissemination of this false, misleading and deceptive advertising message, correct the false and misleading perception it has created in the minds of consumers, and obtain redress for those who have purchased the Cosamin products. Based on violations of state unfair competition laws and Defendant's breach of express warranty, Plaintiff seeks injunctive and monetary relief for consumers who purchased the Cosamin products.

JURISDICTION AND VENUE

- 8. This Court has original jurisdiction pursuant to 28 U.S.C. §1332(d)(2). The matter in controversy, exclusive of interest and costs, exceeds the sum or value of \$5,000,000 and is a class action in which there are in excess of 100 class members and many members of the Class are citizens of a state different from Defendants.
- 9. This Court has personal jurisdiction over Defendants because Defendants are authorized to conduct and do conduct business in California. Defendants have marketed, promoted, distributed, and sold the Cosamin product in California and Defendants have sufficient minimum contacts with this State and/or sufficiently avail themselves of the markets in this State through its promotion, sales, distribution and marketing within this State to render the exercise of jurisdiction by this Court permissible.
- 10. Venue is proper in this Court pursuant to 28 U.S.C. §§1391(a) and (b) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred while he resided in this judicial district. Venue is also proper under 18 U.S.C. §1965(a) because Defendants transact substantial business in this District.

PARTIES

11. Plaintiff Robert Dorfman resides in San Diego County, California. In or around October of 2012, Plaintiff was exposed to and saw the representations described herein regarding the joint health benefits of Cosamin

DS by reading the Cosamin DS product label in a Rite-Aid store near his home in
Del Mar, California. Thereafter, Plaintiff was again exposed to and saw the
representations described herein regarding the joint health benefits of Cosamin
DS by reading the Cosamin DS product label in a Wal-Mart store located in San
Diego, California. In reliance on the claims listed on the product label described
herein and above, and specifically those claims listed on the front of the product
label, that Cosamin would, "protect his cartilage" and "reduce his joint pain,"
Plaintiff purchased the Cosamin DS product at a Rite-Aid store located near his
home in Del Mar, California, and at a Wal-Mart located at 4840 Shawline Street,
San Diego, California 92111. He paid approximately \$35.00 for the product at
Rite-Aid. He paid approximately \$25.00 for the product at Wal-Mart. On each
occasion, Mr. Dorfman purchased the product believing it would provide the
advertised joint health benefits and improve his joint soreness and comfort. As a
result of his purchase, Plaintiff suffered injury in fact and lost money. Had
Plaintiff known the truth about Defendants' misrepresentations and omissions, he
would not have purchased the Cosamin DS product. Plaintiff Dorfman is not
claiming physical harm or seeking the recovery of personal injury damages.

- 12. Defendant Nutramax Laboratories, Inc. is incorporated under the laws of the state of Maryland. Nutramax's corporate headquarters is located at 2208 Lakeside Boulevard, Edgewood, Maryland 21040. Nutramax researches, develops, manufactures, distributes, markets and sells nutritional supplements products across the United States and internationally. Nutramax marketed and sold the Cosamin products to tens of thousands of consumers in California.
- 13. Defendant Rite-Aid Corporation ("Rite-Aid") is one of the nation's largest drugstore chains with more than 4,600 stores in 31 states and the District of Columbia. Rite-Aid is a Delaware corporation headquartered in Camp Hill, Pennsylvania. During the Class period, Rite-Aid promoted, marketed and sold the Cosamin products throughout the United States and in the State of California.

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

1 14. Defendant Wal-Mart Stores, Inc. ("Wal-Mart") is one of the world's 2 largest retailers. Wal-Mart operates Wal-Mart Discount Stores, Wal-Mart 3 Sam's Club warehouse Supercenters. 4 walmartstores.com, and walmart.com. Wal-Mart is a Delaware corporation with 5 its principal executive offices in Bentonville, Arkansas. During the Class period, 6 Wal-Mart promoted, marketed and sold the Cosamin products throughout the 7 United States and in the State of California.

FACTUAL ALLEGATIONS

stores,

Neighborhood

Markets.

The Cosamin Products

- 15. Nutramax manufactures, distributes, and sells the Cosamin line of dietary supplements. Those products include Cosamin DS and Cosamin ASU. Nutramax began manufacturing, marketing and selling the Cosamin products in 1992.
- 16. The Cosamin products are sold in virtually every major food, drug, and mass retail outlet in the country and online retailers, including, but not limited to: Wal-Mart, BJ's Wholesale Club, CVS, Kroger, and Rite-Aid. The Cosamin products are also sold through online retailers such as walmart.com, riteaid.com costco.com, cvs.com, and walgreens.com.
- Since the Cosamin products' launch, Nutramax has consistently 17. conveyed the message to consumers throughout California that the Cosamin products, with their "exclusive formula" will reduce joint pain and protect joint cartilage of all persons who ingest Cosamin. These claims false and misleading, and are not substantiated by competent scientific evidence.
- 18. The Wal-Mart and Rite-Aid defendants market and sell the Cosamin products at issue, and participated in the dissemination of the representations concerning the efficacy of the Cosamin products and adopted the representations as their own. The Wal-Mart and Rite-Aid defendants entered into marketing and sales agreements with Nutramax to further promote and repeat the false and

to Plaintiff and other members of the Class, the Wal-Mart and Rite-Aid defendants adopted, and are responsible for, the representations Nutramax made on packaging regarding the efficacy of the Cosamin products.

19. The Wal-Mart and Rite-Aid defendants also promote, market and sell their own Wal-Mart and Rite-Aid-branded glucosamine chondroitin

products, which they market for joint health.¹

deceptive statements at issue. By placing the Cosamin products on their store

shelves and on retail websites, and thereafter advertising and selling the Products

- 20. The primary active ingredient in all the Cosamin products is glucosamine hydrochloride. Glucosamine is an amino sugar that the body produces and distributes in cartilage and other connective tissue. Cosamin DS and Cosamin ASU also contain chondroitin sulfate. Chondroitin sulfate is a complex carbohydrate found in the body's connective tissues.
- 21. According to the Mayo Clinic, the signs and symptoms of osteoarthritis include joint pain, joint tenderness, joint stiffness, and the inability to move your joint through its full range of motion.²
- 22. There is no competent scientific evidence that taking glucosamine hydrochloride chondroitin sulfate—let alone through oral administration—results in the body metabolizing it into something that provides the advertised joint

http://shop.riteaid.com/dp/B00009M8K0 (on www.riteaid.com, defendant promotes Rite Aid Glucosamine/Chondroitin/MSM for "promot[ing] joint health" – a claim which it repeats on the product's labeling) (last visited April 10, 2013); http://shop.riteaid.com/dp/B001KYVVHQ (on www.riteaid.com, defendant promotes Rite Aid Brand Advanced Glucosamine Chondroitin + MSM for "promot[ing] joint health" – a claim which it repeats on the product's labeling) (last visited April 10, 2013); http://www.walmart.com/ip/Equate-Glucosamine-Chondroitin-MSM-Dietary-Supplement-80ct/16767866 * (On www.walmart.com, defendant promotes its own Equate-branded Glucosamine Chrondoirtin MSM product, which is "specially formulated and may help to renew cartilage, support the joints comfortably, and lubricate joints." Similarly, on the packaging for its product, Wal-Mart claims it will "support joint comfort," and "rebuild cartilage and lubricate joints.") (last visited April 10, 2013).

http://www.mayoclinic.com/health/osteoarthritis/DS00019/DSECTION=symptoms (last visited April 1, 2013).

health and cartilage benefits, including relieving the major symptoms of arthritis.

- 23. Cosamin ASU contains Nutramax's ASU blend, a combination of avocado/soybean unsaponifiables and soy protein isolate and green tea leaf extract. There is no competent scientific evidence that taking any of these ingredients—let alone through oral administration—results in the body metabolizing them into something that relieves any of the major symptoms of arthritis.
- 24. Contrary to the stated representations on all the Cosamin products' labeling and packaging, Defendant does not possess (and has not possessed) competent scientific evidence that any of these ingredients, taken alone or in combination, are effective in providing the advertised joint health and cartilage benefits, including treating the major symptoms of arthritis or any other joint related ailments.
- 25. Despite scientific studies which demonstrate that the claims are false and deceptive, and no scientifically valid confirmation that the Cosamin products are an effective "joint health supplement"—let alone an effective treatment for *all* joints in the human body, for customers of *all* ages and for *all* stages of joint disease—Nutramax states on the Cosamin products' packaging and labeling that Cosamin is a "Joint Health Supplement" that will "reduce joint pain" and "protect cartilage cells from breakdown." Representative Cosamin DS and Cosamin ASU product packaging and labeling appears as follows:

///

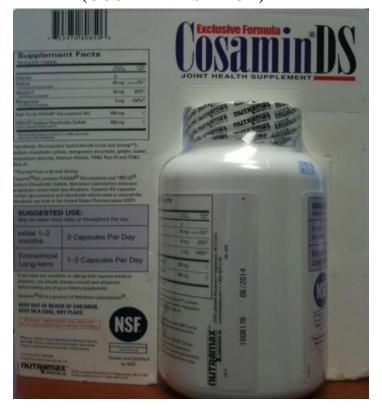
(COSAMIN DS FRONT)

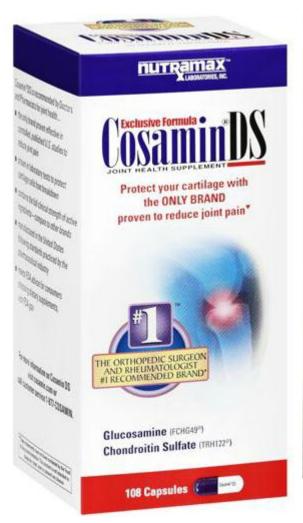


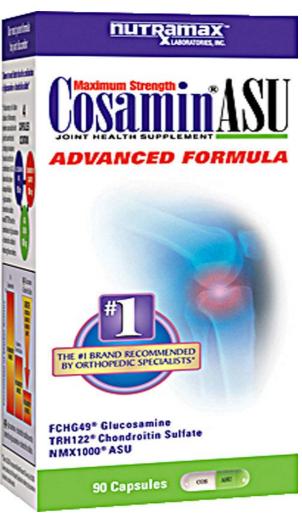
The ONLY brand proven
effective in controlled,
published U.S. studies to
reduce joint pain.
Shown in laboratory tests
to protect cartilage cells
from breakdown.



(COSAMIN DS BACK)







See also Exhibit A attached (Cosamin product packaging and labeling exemplars containing the false and deceptive statements).

- 26. Nutramax's statements on its website repeat and reinforce the false and misleading joint health statements made on the packaging and labeling:
 - Shown in laboratory tests to PROTECT CARTILAGE cells from breakdown
 - The ONLY brand proven effective in controlled, published U.S. clinical studies to reduce joint pain

- Cosamin DS is the #1 Brand Recommended by Orthopedic Specialists. As a joint health supplement, Cosamin DS helps reduce joint pain and stiffness by using ingredients that are safe, effective, and easily absorbed. Cosamin DS is superior to all other brands and has been proven effective in published clinical studies.
- Cosamin is shown effective in peer-reviewed, controlled, published U.S. research.
- 27. The Cosamin television commercials repeat the same advertising message. For example, one commercial includes the following statements:

Pharmacist Bob Henderson created Cosamin DS – the only glucosamine chondroitin brand proven to reduce joint pain. Now we've added ASU to make a more advanced formula to combat joint discomfort and cartilage breakdown. Cosamin – the number one brand recommended by orthopedic specialists. Anything less just isn't the best.

- 28. Likewise, in addition to providing pictures of the false and deceptive packaging and labeling for the Cosamin products, Wal-Mart makes additional statements on its website that repeat and reinforce the false and misleading joint health statements made on the packaging and labeling.
 - 29. Wal-Mart's advertising statements about Cosamin DS include:
 - These joint supplements use ingredients that are safe to use and that get easily absorbed into your bloodstream. The main ingredient being chondroitin sulfate, these tablets provides cartilage its fluidity and elasticity. The tablets greatly help in protecting your damaged cartilage, thereby help reduce stiffness in your joints. These chondroitin sulfate capsules are easy to swallow. Highly recommended by orthopedic surgeons and rheumatologists, these capsules help maintain healthy and pain-free bone joints.
 - Orthopedic surgeon and Rheumatologist recommended

2
3
4

5 6

8

10 11

12

13

14

16

15

1718

1920

21

2223

24

25

26

2728

• Contains the exclusive chondroitin sulfate selected by the National Institutes of Health for the GAIT study

- Take this Cosamin DS Joint Health Supplement to support your joint health. These Cosamin DS capsules are the only brand that contains pharmaceutical-grade TRH122 chondroitin sulfate and FCHG49 glucosamine. This is why these glucosamine chondroitin supplements from Cosamin DS are a recommended brand from orthopedic surgeons and rheumatologists. This joint health supplement isn't only effective, but it comes in easy-to-swallow capsules, as well
- Supports joint health
- Only brand that contains pharmaceutical-grade TRH122 chondroitin sulfate and FCHG49 glucosamine³
- 30. Wal-Mart's advertising statements about Cosamin ASU include:
- The Cosamin ASU Supplement is designed with active people in mind. As the number one brand recommended by orthopedic specialists, Cosamin ASU Advanced Formula is a comprehensive and complete joint support supplement. The joint health supplement has dual synergy and triple action. The four capsules in this joint pain supplement contain glucosamine and chondroitin sulfate. Start planning for the future and for your health by taking this Cosamin ASU Supplement, Advanced Formula (90ct).
- For active people with joint discomfort
- #1 brand recommended by orthopedic specialists⁴

³ http://www.walmart.com/ip/Cosamin-Ds-Exclusive-Formula-Joint-Health-Supplement-60-ct/12556805 (last visited April 10, 2013).

⁴ http://www.walmart.com/ip/Cosamin-ASU-Joint-Health-Supplement-Advanced-Formula- 90ct/15033106?findingMethod=Recommendation: wm:RecentlyViewedItems (last visited April 10, 2013).

REARDON, LLP	
0'R	
\circ	
ઝ	
HURST	
OD	
BLO	

Case 1:14-cv-00124-JFM Document 1 Filed 04/11/13 Page 13 of 32
31. Likewise, in addition to providing pictures of the false and
deceptive packaging and labeling for the Cosamin products, Rite-Aid makes
additional statements on its website that repeat and reinforce the false and
misleading joint health statements made on the packaging and labeling.
32. Rite-Aid's advertising statements about Cosamin DS include:
 Premium dietary supplement for joint health
• Joint Health Supplement. Exclusive Formula.
• Protect your cartilage with the only brand proven to reduce joint pain.
• The No. 1 brand recommended by orthopedic specialists.
 Helps your joints last longer.
• Cosamin DS is recommended by Doctors and Pharmacists for joint

reduce joint pain.

Shown in laboratory tests to protect cartilage from breakdown.

• Contains the full clinical strength of active ingredients-compare to other brands,

The only brand proven effective in controlled, published U.S. studies to

- Manufactured in the United States following standards practiced by the pharmaceutical industry.
- Tested and certified by NSF.

health.

- The original researched brand.
- Cosamin DS contains FCHG49 Glucosamine and TRH122 sodium chondroitin sulfate, Nutramax Laboratories exclusive proprietary researched specifications.⁵
- 33. Rite-Aid's advertising statements about Cosamin ASU include:
- Joint Health Supplement.

5 http://shop.riteaid.com/dp/B002LL7B5I (last visited April 10, 2013).

LLP	
DON,	
O'REAR	
8	
HURST	
[TOOD]	
$\mathbf{B}_{\mathbf{I}}$	

- The No. 1 brand recommended by orthopedic surgeons.
- Our most potent formula for joint discomfort.
- Shown to work better than the combination of glucosamine + chondroitin sulfate (In laboratory cell culture studies of inflammatory markers associated with joint discomfort and cartilage breakdown, it was found that the combination of ASU [avocado/soybean/unsaponifiables] + glucosamine + chondroitin sulfate was better than the combination of glucosamine + chondroitin sulfate in reducing these markers).
- Help your joints last longer.
- Cosamin ASU is the most complete and comprehensive joint support supplement available; is supported by US published research; is manufactured in the United States following standards practiced in the pharmaceutical industry; contains decaffeinated green tea extract for antioxidant health benefits.
- Tested & certified by NSF.⁶

 Scientific Studies Confirm That Cosamin Is Not Effective And

 Defendants' Health Benefits Message Is False And Deceptive
- 34. Contrary to the stated representations on all the Products' labeling and packaging, and throughout Defendants' other advertising and marketing for the Products, Defendants do not possess (and has not possessed) competent scientific evidence that any of these ingredients, taken alone or in combination, are effective in treating the major symptoms of arthritis or any other joint related ailments.
- 35. Defendants knew or should have known that glucosamine alone and taken in combination with the other ingredients present in Cosamin have no

⁶ http://shop.riteaid.com/dp/B001CLBA50 (last visited April 10, 2013).

actual medicinal value and do not provide any of the warranted benefits as represented by Defendants' Cosamin products' packaging, labeling and other advertising. In fact, there is no scientific study demonstrating that any glucosamine product can regenerate cartilage. To the contrary, as numerous studies have confirmed, neither glucosamine, chondroitin, nor any other supplements or ingredients actually regenerate cartilage or provide joint comfort or relief from pain.

- 36. For example, a 1999 study involving 100 subjects by Houpt *et al.*, entitled *Effect of glucosamine hydrochloride in the treatment of pain of osteoarthritis of the knee*, 26(11) J. Rheumatol. 2423-30 (1999), found that glucosamine hydrochloride performed no better than placebo at reducing pain at the conclusion of the eight week trial.
- 37. In February 2004, a Supplement to the American Journal of Orthopedics published an article entitled "Restoring Articular Cartilage in the Knee." The authors concluded that adult cartilage cannot be regenerated because it is not vascularized, meaning that blood does not flow to damaged cartilage which prevents any mechanism for regeneration.
- 38. Likewise, a 2004 study by McAlindon, *et al.*, entitled, *Effectiveness of Glucosamine For Symptoms of Knee Osteoarthritis: Results From and Internet-Based Randomized Double-Blind Controlled Trial*, 117(9) Am. J. Med. 649-9 (Nov. 2004), concluded that "glucosamine was no more effective than placebo in treating symptoms of knee osteoarthritis" in short, that glucosamine is ineffective. *Id.* at 646 ("we found no difference between the glucosamine and placebo groups in any of the outcome measures, at any of the assessment time points").
- 39. A 2004 study by Cibere, et al., entitled, "Randomized, Double-Blind, Placebo-Controlled Glucosamine Discontinuation Trial In Knee Osteoarthritis", 51(5) Arthritis Care & Research 738-45 (Oct. 15, 2004), studied

CLASS ACTION COMPLAINT

users of glucosamine who had claimed to have experienced at least moderate
improvement after starting glucosamine. These patients were divided into two
groups - one that continued using glucosamine and one that was given a placebo
For six months, the primary outcome observed was the proportion of disease
flares in the glucosamine and placebo groups. A secondary outcome was the
time to disease flare. The study results reflected that there were no differences in
either the primary or secondary outcomes for glucosamine and placebo. The
authors concluded that the study provided no evidence of symptomatic benefit
from continued use of glucosamine - in other words, any prior perceived benefits
were due to the placebo effect and not glucosamine. Id. at 743 ("In this study
we found that knee OA disease flare occurred as frequently, as quickly, and as
severely in patients who were randomized to continue receiving glucosamine
compared with those who received placebo. As a result, the efficacy of
glucosamine as a symptom-modifying drug in knee OA is not supported by our
study.").

- 40. A large (1,583 subjects), 24-week, multi-center RCT study sponsored by the National Institute of Health ("NIH"), published in the New England Journal of Medicine (the "2006 GAIT Study"), concluded: "[t]he analysis of the primary outcome measure did not show that either [glucosamine or chondroitin], alone or in combination, was efficacious. . . ." Clegg, D., *et al.*, Glucosamine, Chondroitin Sulfate, and the Two in Combination for Painful Knee Osteoarthritis, 354 New England J. of Med. 795, 806 (2006).
- 41. The 2006 GAIT Study authors rigorously evaluated the effectiveness of glucosamine hydrochloride and chondroitin, alone and in combination, on osteoarthritis for six months. According to the study's authors, "[t]he analysis of the primary outcome measure did not show that either supplement, alone or in combination, was efficacious. . . ." 2006 GAIT Study at 806.

- 1 2 3 4 5 6 7 8 9 10

- 42. Subsequent GAIT studies in 2008 and 2010 reported that glucosamine and chondroitin did not rebuild cartilage and were otherwise ineffective even in patients with moderate to severe knee pain for which the 2006 reported results were inconclusive. See Sawitzke, A.D., et al., The Effect of Glucosamine and/or Chondroitin Sulfate on the Progression of Knee Osteoarthritis: A GAIT Report, 58(10) J. Arthritis Rheum. 3183-91 (Oct. 2008); Sawitzke, A.D., Clinical Efficacy And Safety Of Glucosamine, Chondroitin Sulphate, Their Combination, Celecoxib Or Placebo Taken To Treat Osteoarthritis Of The Knee: 2 Year Results From GAIT, 69(8) Ann Rhem. Dis. 1459-64 (Aug. 2010).
- 43. The GAIT studies are consistent with the reported results of prior and subsequent studies. For example, the National Collaborating Centre for Chronic Conditions ("NCCCC") reported "the evidence to support the efficacy of glucosamine hydrochloride as a symptom modifier is poor" and the "evidence for efficacy of chondroitin was less convincing." NCCCC, Osteoarthritis National Clinical Guideline for Care and Management of Adults, Royal College of Physicians, London 2008. Consistent with its lack of efficacy findings, the NCCCC Guideline did not recommend the use of glucosamine or chondroitin for treating osteoarthritis. *Id.* at 33.
- 44. In a 2007 report, Vlad, *et al.* reviewed all studies involving glucosamine hydrochloride and concluded that "[g]lucosamine hydrochloride is not effective." Glucosamine for Pain in Osteoarthritis, 56:7 Arthritis Rheum. 2267-77 (2007); *see also id.* at 2275 ("we believe that there is sufficient information to conclude that glucosamine hydrochloride lacks efficacy for pain in OA").
- 45. In October 2008, the American College of Rheumatology's Journal, Arthritis & Rheumatism published a report on a double blind study conducted at multiple centers in the United States examining joint space width loss with

CLASS ACTION COMPLAINT

2
 3
 4

radiograph films in patients who were treated with glucosamine hydrochloride. The authors concluded that after two years of treatment with this supplement, the treatment did not demonstrate a clinically important difference in joint space width loss. Sawitzke *et al.*, Glucosamine for Pain in Osteoarthritis: Why do Trial Results Differ?, Arthritis Rheum., 58:3183-3191 (2008).

- 46. In December 2008, the American Academy of Orthopaedic Surgeons published clinical practice guidelines for the "Treatment of Osteoarthritis of the Knee (Non-Arthroplasty)," and recommended that "glucosamine and sulfate or hydrochloride should not be prescribed for patients with symptomatic OA of the knee." Richmond *et al.*, *Treatment of osteoarthritis of the knee* (nonarthroplasty), J. Am. Acad. Orthop. Surg. Vol. 17 No. 9 591-600 (2009). This recommendation was based on a 2007 report from the Agency for Healthcare Research and Quality (AHRQ), which states that "the best available evidence found that glucosamine hydrochloride, chondroitin sulfate, or their combination did not have any clinical benefit in patients with primary OA of the knee." Samson, *et al.*, *Treatment of Primary and Secondary Osteoarthritis of the Knee, Agency for Healthcare Research and Quality*, 2007 Sep 1. Report No. 157.
- 47. Even studies not concerning the type of glucosamine in the Cosamin Products demonstrate that glucosamine does not provide the joint health benefits that Defendants represent. For example, a study by Rozendaal, *et al.*, entitled, *Effect of Glucosamine Sulfate on Hip Osteoarthritis*, 148 Ann. of Intern. Med. 268-77 (2008), assessing the effectiveness of glucosamine on the symptoms and structural progression of hip osteoarthritis during two years of treatment, concluded that glucosamine was no better than placebo in reducing symptoms and progression of hip osteoarthritis.
- 48. In March 2009, Harvard Medical School published a study conclusively proving that the ingestion of glucosamine could not affect the growth of cartilage. The study took note of the foregoing 2006 and 2008 studies,

which "cast considerable doubt" upon the value of glucosamine. The authors went on to conduct an independent study of subjects ingesting 1500 mg of glucosamine, and proved that *only trace amounts of glucosamine* entered the human serum, far below any amount that could possibly affect cartilage (emphasis added). Moreover, even those trace amounts were present only for a few hours after ingestion. The authors noted that a 1986 study had found no glucosamine in human plasma after ingestion of four times the usual 1500 mg of glucosamine chloride or sulphate. Silbert, Dietary Glucosamine Under Question, Glycobiology 19(6):564-567 (2009).

- 49. In April 2009, the Journal of Orthopedic Surgery published an article entitled, "*Review Article: Glucosamine*." The article's authors concluded that, based on their literature review, there was "little or no evidence" to suggest that glucosamine was superior to a placebo even in slowing down cartilage deterioration, much less regenerating it. Kirkham, *et al.*, Review Article: Glucosamine, Journal of Orthopedic Surgery, 17(1): 72-6 (2009).
- 50. In 2009, a panel of scientists from the European Food Safety Authority ("EFSA") (a panel established by the European Union to provide independent scientific advice to improve food safety and consumer protection), reviewed nineteen studies submitted by an applicant, and concluded that "a cause and effect relationship has not been established between the consumption of glucosamine hydrochloride and a reduced rate of cartilage degeneration in individuals without osteoarthritis." EFSA Panel on Dietetic Products, Nutrition and Allergies, *Scientific Opinion on the substantiation of a health claim related to glucosamine hydrochloride and reduced rate of cartilage degeneration and reduced risk of osteoarthritis*, EFSA Journal (2009), 7(10):1358.
- 51. In a separate opinion from 2009, an EFSA panel examined the evidence for glucosamine (either hydrochloride or sulfate) alone or in combination with chondroitin sulfate and maintenance of joints. The claimed

effect was "joint health," and the proposed claims included "helps to maintain
healthy joint," "supports mobility," and "helps to keep joints supple and
flexible." Based on its review of eleven human intervention studies, three meta-
analyses, 21 reviews and background papers, two animal studies, one in vitro
study, one short report, and one case report, the EFSA panel concluded that "a
cause and effect relationship has not been established between the consumption
of glucosamine (either as glucosamine hydrochloride or as glucosamine
sulphate), either alone or in combination with chondroitin sulphate, and the
maintenance of normal joints." EFSA Panel on Dietetic Products, Nutrition and
Allergies, Scientific Opinion on the substantiation of health claims related to
glucosamine alone or in combination with chondroitin sulphate and maintenance
of joints and reduction of inflammation, EFSA Journal (2009), 7(9):1264.

- 52. A 2010 meta-analysis by Wandel, et al., entitled Effects of Glucosamine, Chondroitin, Or Placebo In Patients With Osteoarthritis Of Hip Or Knee: Network Meta- Analysis, BMJ 341:c4675 (2010), examined prior studies involving glucosamine and chondroitin, alone or in combination, and whether they relieved the symptoms or progression of arthritis of the knee or hip. The study authors reported that glucosamine and chondroitin, alone or in combination, did not reduce joint pain or have an impact on the narrowing of joint space: "Our findings indicate that glucosamine, chondroitin, and their combination do not result in a relevant reduction of joint pain nor affect joint space narrowing compared with placebo." Id. at 8. The authors further concluded "[w]e believe it unlikely that future trials will show a clinically relevant benefit of any of the evaluated preparations." Id.
- 53. On July 7, 2010, Wilkens, *et al.*, reported that there was no difference between placebo and glucosamine for the treatment of low back pain and lumbar osteoarthritis and that neither glucosamine, nor a placebo, were effective in reducing pain related disability. The researchers also concluded that,

"Based on our results, it seems unwise to recommend glucosamine to all patients" with low back pain and lumbar osteoarthritis. Wilkens, *et al.*, *Effect of Glucosamine on Pain-Related Disability in Patients With Chronic Low Back Pain and Degenerative Lumbar Osteoarthritis*, 304(1) JAMA 45-52 (July 7, 2010).

- 54. In 2011, Miller and Clegg, after surveying the clinical study history of glucosamine and chondroitin, concluded that, "[t]he cost-effectiveness of these dietary supplements alone or in combination in the treatment of OA has not been demonstrated in North America." Miller, K. and Clegg, D., *Glucosamine and Chondroitin Sulfate*, Rheum. Dis. Clin. N. Am. 37 103-118 (2011).
- 55. In June 2011, the Journal of Pharmacy & Pharmaceutical Sciences published an article entitled, "The Glucosamine Controversy; A Pharmacokinetic Issue." The authors concluded that regardless of the formulation used, no or marginal beneficial effects were observed as a result of low glucosamine bioavailability. Aghazadeh-Habashi and Jamali, The Glucosamine Controversy; A Pharmacokinetic Issue, Journal of Pharmacy & Pharmaceutical Sciences, 14(2): 264-273 (2011).
- 56. In 2012, a report by Rovati, et al. entitled Crystalline glucosamine sulfate in the management of knee osteoarthritis: efficacy, safety, and pharmacokinetic properties, Ther Adv Muskoloskel Dis 4(3) 167-180, noted that glucosamine hydrochloride "ha[s] never been shown to be effective."
- 57. In 2012, EFSA examined the evidence to determine if glucosamine sulphate or glucosamine hydrochloride could substantiate a claimed effect of "contributes to the maintenance of normal joint cartilage." Based on its review of 61 references provided by Merck Consumer Healthcare, the EFSA panel concluded that "a cause and effect relationship has not been established between the consumption of glucosamine and maintenance of normal joint cartilage in individuals without osteoarthritis." EFSA Panel on Dietetic Products, Nutrition

_
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

2

and Allergies, Scientific Opinion on the substantiation of a hea	alth claim relatea
to glucosamine and maintenance of normal joint cartilage, EF	SA Journal 2012
10(5): 2691.	

58. The studies identified by Nutramax on its website are fundamentally flawed, not scientifically valid and/or possess obvious, unmitigated bias, *i.e.* the study itself was sponsored by Nutramax. For example:

Cosamin ASU research & review articles

(as identified on Nutramax's website: http://www.nutramaxlabs.com/index.php/2012-06-20-17-18-09/research-citations) (Last viewed 04/08/2013).

• Au RY, Al-Talib TK, Au AY, et al., Osteoarthritis and Cartilage 2007;15(11):1249-1255.

This study was conducted with the support of two employees of Defendant Nutramax, and did not involve any formulation of glucosamine, nor chondroitin. Instead, it studied the effect of avocado soybean unsaponifiables on human cells in a laboratory.

• Au R, Au A, Rashmir-Raven A, Frondoza CG. *The FASEB Journal* 2007;21(6):A736.

This study was "supported by Nutramax Laboratories, and at least one employees of Nutramax contributed to its findings. The study was conducted on Horse and Human cells in a laboratory, and the findings were totally unreliable, and conclusive at best: "Our study supports the *potential* clinical utility of the combination of ASU, Glu, and CS in suppressing inflammation." (emphasis added).

• Au A, Au R, Kramer E, et al., The FASEB Journal 2007;21(6):A736.

This Study was not performed on any on either of the key ingredients, glucosamine or chondroitin sulfate.

• Au AY, Polotsky M, Au RY, et al., Proceedings, 35th Annual Conference Veterinary Orthopedic Society 2008,56.

This was a conference; not a clinical study.

26

27

28

Cosamin DS Clinical Trials

• Das AK, Hammad TA. Osteoarthritis and Cartilage 2000;8(5):343-350.

This was not an independent clinical trial; it was co-sponsored by Nutramax Laboratories. Even accounting for the inherent bias in this study, the WOMAC score, described as a measurement for the "severity of pain," did not produce "statistically significant" improvements in pain reduction amongst the study participants. *Id.* at p. 347.

• Leffler CT, Philippi AF, Leffler SG, et al., Military Medicine 1999;164(2):85-91.

This purported "clinical" trial involved only 34 male participants treating "degenerative joint disease of the knee and low back. The methodology performed was not scientifically valid as it weighed the participants' subjective responses and measured improvements in physical activity (running times). It made no finding regarding benefits for treating spinal degenerative joint disease.

• Van Blitterswijk WJ, van de Nes JCM, Wuisman PIJM. BMC *Complementary and Alternative Medicine* 2003, 3:2.

This was not clinical trial; it was merely a medical case report of a <u>single</u> patient who consumed Defendant's product. The authors reached no definitive conclusion, stating only, "[I]t is justified to conduct more definitive trials focusing on (disc) cartilage morphology, to unambiguously prove or disprove the beneficial affects of these supplements."

• Scroggie DA, Albright A, Harris MD. *Archives of Internal Medicine* 2003. Vol. 163(13): 1587-1590.

This study was not designed to test the efficacy of oral glucosamine consumption, but instead it was designed to determine whether consumption of glucosamine altered glucose metabolism in patients with type 2 diabetes.

59. To date, there are only two studies, both of which are more than a decade old and analyze a form of glucosamine not in the Cosamin products, purporting to claim that the ingestion of glucosamine can affect the growth or deterioration of cartilage, both sponsored by a glucosamine supplement

manufacturer: Pavelka *et al.*, Glucosamine Sulfate Use and Delay of Progression of Knee Osteoarthritis, Arch. Intern. Med., 162: 2113-2123 (2002); Reginster *et al.*, Long-term Effects of Glucosamine Sulphate On Osteoarthritis Progress: A Randomised, Placebo-Controlled Clinical Trial, Lancet, 357: 251-6 (2001). As noted in the April 2009 Journal of Orthopedic Surgery article, the methodologies in those studies had "inherently poor reproducibility," and even minor changes in posture by the subjects during scans could cause false apparent changes in cartilage. The authors of the Journal of Orthopedic Surgery article explained the manufacturer-sponsored studies' findings by noting that "industry-sponsored trials report positive effects more often than do non-sponsored trials and more find pro-industry results." Moreover, neither study examined the form of glucosamine in the Products – glucosamine hydrochloride. In fact, no reliable scientific medical study has shown that glucosamine hydrochloride and chondroitin, alone or in combination, have a structure modifying effect that will regenerate cartilage that has broken down or worn away.

60. Plaintiff and Class members have been and will continue to be deceived or misled by Defendants' deceptive representations touting the effectiveness of the Cosamin products. Plaintiff purchased and used the Cosamin products during the Class Period and in doing so, read, considered and based his decisions to buy Cosamin on the above cited label representations. Because the Cosamin products' sole purpose is to provide joint relief for the major symptoms of arthritis, Defendants' representations and omissions were a material factor in influencing Plaintiff's decision to purchase Cosamin. There is no other reason for Plaintiff to have purchased Cosamin and Plaintiff would not have purchased Cosamin had he known that Cosamin was ineffective and Defendants did not possess competent scientific evidence to support the claims that it made about Cosamin.

61. As a result, Plaintiff and the Class members have been damaged in

9
10
11
12
13
14
15
16
17
18
19
20
21

2

3

4

5

6

8

their purchases of the Cosamin products and have been deceived into purchasing products that they believed, based on Defendants' representations, were proven to be effective in treating the major symptoms of arthritis and other joint related ailments when, in fact, they are not.

62. Defendants, by contrast, reaped enormous profits from their false marketing and sale of the Cosamin products.

CLASS DEFINITION AND ALLEGATIONS

63. Plaintiff brings this action on behalf of himself and all other similarly situated pursuant to Rule 23(a), (b)(2), and (b)(3)of the Federal Rules of Civil Procedure and seeks certification of the following Class:

All persons who purchased the Cosamin Products in California.⁷ Excluded from the Class are Defendants, their parents, subsidiaries, affiliates, officers and directors, those who purchased the Cosamin products for the purpose of resale, and those who assert claims for personal injury.

- 64. Members of the Class are so numerous and geographically dispersed that joinder of all Class members is impracticable. Plaintiff is informed and believes, and on that basis alleges, that the proposed Class contains many thousands of members. The precise number of Class members is unknown to Plaintiff.
- 65. Common questions of law and fact exist as to all members of the Class and predominate over questions affecting only individual Class members. The common legal and factual questions include, but are not limited to, the following:
 - Whether Defendants had competent scientific evidence to support each of the claims that it made about the Cosamin products;

27

28

22

23

24

25

26

7 The Cosamin products include: (1) Cosamin DS; and (2)Cosamin ASU.

5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
2728

2

ii.	Whether the claims discussed herein that Defendants made
	about the Cosamin products were or are false, misleading, or
	reasonably likely to deceive:

- iii. Whether Defendants' alleged conduct violates public policy;
- iv. Whether the alleged conduct constitutes violations of the laws asserted herein;
- v. Whether Defendants engaged in false and misleading advertising;
- vi. Whether Plaintiff and Class members have sustained monetary loss and the proper measure of that loss;
- vii. Whether Plaintiff and Class members are entitled to restitution, disgorgement of Defendants' profits, declaratory and/or injunctive relief; and
- viii. Whether Plaintiff and Class members are entitled to an award of compensatory damages.
- 66. The claims asserted by Plaintiff in this action are typical of the claims of the members of the Class, as the claims arise from the same course of conduct by Defendants, and the relief sought is common. Plaintiff and Class members suffered uniform damages caused by their purchase of the Cosamin products manufactured, marketed, and sold by Defendants.
- 67. Plaintiff will fairly and adequately represent and protect the interests of the members of the Class. Plaintiff has retained counsel competent and experienced in both consumer protection and class litigation.
- 68. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The expense and burden of individual litigation would make it impracticable or impossible for proposed Class members to prosecute their claims individually. It would thus be virtually impossible for the Class, on an individual basis, to obtain effective redress for the wrongs done

to them. Furthermore, even if Class members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances here.

69. In the alternative, the Class also may be certified because Defendants have acted or refused to act on grounds generally applicable to the Class thereby making final declaratory and/or injunctive relief with respect to the members of the Class as a whole appropriate.

COUNT I

Violation of the Consumers Legal Remedies Act –Civil Code §1750 et seq.

- 70. Plaintiff seeks preliminary and permanent injunctive and equitable relief on behalf of the entire Class, on grounds generally applicable to the entire Class, to enjoin and prevent Defendants from engaging in the acts described, and requiring Defendants to provide full restitution to Plaintiff and Class members.
- 71. Unless a Class is certified, Defendants will retain monies that were taken from Plaintiff and Class members as a result of their conduct. Unless a Class-wide injunction is issued, Defendants will continue to commit the violations alleged, and the members of the Class and the general public will continue to be misled.
- 72. Plaintiff re-alleges and incorporates by reference the allegations contained in the paragraphs above as if fully set forth herein.
- 73. This cause of action is brought under the Consumers Legal Remedies Act, California Civil Code §1750, et seq. (the "Act"). Plaintiff is a

5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27

2

3

4

consumer as defined by California Civil Code §1761(d).	Defendant's Cosamin
products are goods within the meaning of the Act.	

- 74. Defendants violated and continues to violate the Act by engaging in the following practices proscribed by California Civil Code §1770(a) in transactions with Plaintiff and the Class which were intended to result in, and did result in, the sale of the Cosamin products:
 - (5) Representing that [the Products] have... approval, characteristics,... uses [and] benefits... which [they do] not have....

* * *

(7) Representing that [the Products] are of a particular standard, quality or grade . . . if [they are] of another.

* * *

(9) Advertising goods . . . with intent not to sell them as advertised.

* * *

- (16) Representing that [the Products have] been supplied in accordance with a previous representation when [they have] not.
- 75. Defendants violated and continue to violate the Act by representing and failing to disclose material facts on the Cosamin product labels and packages as described above when they knew, or should have known, that the representations were unsubstantiated, false and misleading and that the omissions were of material facts.
- 76. Pursuant to §1782(d) of the Act, Plaintiff and the Class seek a court order enjoining the above-described wrongful acts and practices of Defendants and for restitution and disgorgement.
- 77. Pursuant to §1782 of the Act, Plaintiff notified Defendants in writing by certified mail of the particular violations of §1770 of the Act and demanded that Defendants rectify the problems associated with the actions detailed above and give notice to all affected consumers of Defendants' intent to so act. Copies of the letters are attached hereto as Exhibit B.

28

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

BLOOD HURST & O'REARDON, LLP		
+		

78. If Defendants fail to rectify or agree to rectify the problems
associated with the actions detailed above and give notice to all affected
consumers within 30 days of the date of written notice pursuant to §1782 of the
Act, Plaintiff will amend this complaint to add claims for actual, punitive and
statutory damages, as appropriate.

- 79. Defendants' conduct is malicious, fraudulent and wanton, and provides misleading information.
- 80. Pursuant to §1780(d) of the Act, attached hereto as Exhibit C is the affidavit showing that this action has been commenced in the proper forum.

COUNT II

Violation of Business & Professions Code §17200, et seq.

- 81. Plaintiff re-alleges and incorporates by reference the allegations contained in the paragraphs above as if fully set forth herein.
- As alleged herein, Plaintiff has suffered injury in fact and lost 82. money or property as a result of Defendants' conduct because he purchased the Products.
- In the course of conducting business, Defendants committed 83. unlawful business practices by, *inter alia*, making the representations (which also constitute advertising within the meaning of §17200) and omissions of material facts, as set forth more fully herein, and violating Civil Code §§1572, 1573, 1709, 1711, 1770, Business & Professions Code §§17200, et seq., 17500, et seq., and the common law.
- Plaintiff and the Class reserve the right to allege other violations of law, which constitute other unlawful business acts or practices. Such conduct is ongoing and continues to this date.
- 85. Defendants' acts, omissions, misrepresentations, practices and nondisclosures as alleged herein also constitute "unfair" business acts and practices within the meaning of Business and Professions Code §17200 et seq., in that

their conduct is substantially injurious to consumers, offends public policy, and is immoral, unethical, oppressive, and unscrupulous as the gravity of the conduct outweighs any alleged benefits attributable to such conduct.

86 As stated in this complaint. Plaintiff alleges violations of consumer.

- 86. As stated in this complaint, Plaintiff alleges violations of consumer protection, unfair competition and truth in advertising laws resulting in harm to consumers. Plaintiff asserts violations of the public policy of engaging in false and misleading advertising, unfair competition and deceptive conduct towards consumers. This conduct constitutes violations of the unfair prong of Business & Professions Code §17200 *et seq*.
- 87. There were reasonably available alternatives to further Defendants' legitimate business interests, other than the conduct described herein.
- 88. Defendants' claims, nondisclosures and misleading statements, as more fully set forth above, are also false, misleading and/or likely to deceive the consuming public within the meaning of Business & Professions Code §17200 *et seq*.
- 89. Defendants' labeling and packaging as described herein, also constitutes unfair, deceptive, untrue and misleading advertising.
- 90. Defendants' conduct caused and continues to cause substantial injury to Plaintiff and the other Class members. Plaintiff has suffered injury in fact and has lost money as a result of Defendants' unfair conduct.
- 91. Plaintiff, on behalf of himself, and all other similarly situated California residents, seeks restitution of all money obtained from Plaintiff and the members of the Class collected as a result of unfair competition, an injunction prohibiting Defendants from continuing such practices, corrective advertising and all other relief this Court deems appropriate, consistent with Business & Professions Code §17203.

COUNT III

Breach of Express Warranty

- 92. Plaintiff re-alleges and incorporates by reference the allegations contained in the paragraphs above as if fully set forth herein.
- 93. Plaintiff, and each member of the Class, formed a contract with Defendants at the time Plaintiff and the other members of the Class purchased the Cosamin products. The terms of that contract include the promises and affirmations of fact made by Defendants on the Cosamin product labels and packages, as described above. These representations constitute express warranties, became part of the basis of the bargain, and are part of a standardized contract between Plaintiff and the members of the Class on the one hand, and Defendants on the other.
- 94. All conditions precedent to Defendants' liability under this contract have been performed by Plaintiff and the Class.
- 95. Defendants breached the terms of this contract, including the express warranties, with Plaintiff and the Class by not providing the Cosamin products that could provide the benefits described above which was the only reason Plaintiff and Class members purchased the Cosamin products.
- 96. As a result of Defendants' breach of warranty, Plaintiff and Class members have been damaged in the amount of the purchase price of the Cosamin products they purchased.

PRAYER FOR RELIEF

Wherefore, Plaintiff prays for a judgment:

- A. Certifying the class as requested herein;
- B. Awarding Plaintiff and the proposed Class members damages;
- C. Awarding restitution and disgorgement of Defendants' revenues to Plaintiff and the proposed Class members;
- D. Awarding declaratory and injunctive relief as permitted by law or equity, including enjoining Defendants from continuing the

Case 1:14-cv-00124-JFM Document 1 Filed 04/11/13 Page 32 of 32